



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(54) Title: <b>IMPROVEMENTS IN AND RELATING TO INCONTINENCE SYSTEMS</b></p> <div data-bbox="776 1123 1031 1564" data-label="Image"> </div> <p>(57) Abstract</p> <p>The invention relates to a system for periodically and/or continuously draining the bladder of female patients. The system includes a catheter tube (10) intended for insertion into the urethra of the patient, and a container (23) for collecting the urine discharged from the bladder. The container (23) is connected to the outlet opening of the catheter tube (10), either directly or indirectly. The system is characterized in that the means for fixating the catheter tube (10) in the urethra includes a first compliant collar (13) which is located on the outside of the tube in the region of the opening coacting with the bladder and which is concentric with the longitudinal axis of the tube (10), the first collar being intended to sealingly abut the urethra wall, and further includes a second compliant collar (18) which is located adjacent to or in the vicinity of the region of the outlet opening of the catheter tube (10) such as to form means for restricting the extent to which the tube (10) is inserted into the urethra; and in that the urine collecting container (23) is divided into mutually communicating sections.</p>		

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Improvements in and relating to incontinence systems

The present invention relates generally to an improvement in urine incontinence systems.

- 5 More specifically, but not exclusively, the invention relates to apparatus operative to remove or assist in the discharge of urine from the bladders of female patients, either periodically or continuously. Such apparatus will include a urine catheter in the form of
- 10 an elongated, hollow tubular element, referred to here as a catheter tube, which is intended for insertion into the urethra or urinary tract of a female patient. One open end of the tube is in communication with the bladder and therewith functions as an inlet opening for
- 15 urine present in the bladder. The other open end of the catheter tube functions as an outlet opening through which urine passes from the bladder. The catheter tube includes means by which the tube is fixated within the urethra or urinary tract. Such apparatus will also
- 20 include a container for collecting and storing temporarily the urine that drains from the bladder. The container is connected to the outlet opening of the catheter tube, either directly or indirectly, and is provided in the region of said connection with valve means
- 25 which allows urine to flow in one direction from the catheter tube into the container, but which is operative to prevent the flow of urine in the reverse direction. The lower end of the container incorporates means by which the container can be emptied.
- 30 Apparatus of the aforesaid kind which are intended for the removal of body fluids, particularly urine, and which thus include a drainage tube and a container for the temporary storage of body fluid that drains off are
- 35 well documented in patent literature and are well known

from the practical use of such apparatus in medical care establishments. The present invention thus relates to a catheter tube for internal use, as distinct from commercially available urinals intended for external use. An example of this latter type of catheter is described and illustrated in US-A-3,374,790.

Examples of catheters for the removal or drainage of urine or other body fluids and intended for internal use are found described and illustrated in U.S. Patent Specification Nos. 4,227,533; 3,583,404; 3,595,241 and 3,314,430.

Storage containers for fluids excreted from the body are known from a plurality of patent publications. See, for instance, US-A-3,568,218; DE-OS-26 34 071; GB-A-2.061.103; US-A-3,432,865 and US-A-4,270,213.

An apparatus operative to drain and collect body fluids, preferably urine, is obtained through the combination of a known catheter tube and a known container. As far as is known, medical care establishments have hitherto used this combination technique.

In addition to the known technique described above, the patent literature also teaches portable urine drainage systems or apparatus (see, for instance, US-A-3,703,731) intended solely for use by vehicle-borne persons who may find it difficult to leave the vehicle to urinate in a conventional fashion.

However, there is a progressively increasing number of people who suffer from incontinence with accompanying difficulties and unpleasantness in the form of uncomfortable skin irritation and the increased need of

personal hygiene, this latter including both body hygiene and a frequent change of clothing and bed linen.

When using conventional internal catheters, it is necessary normally for the catheters to be inserted and removed by nursing personnel. When a known urine catheter is combined with a known container, the container may be carried, for instance, on one side of the body of the person suffering from incontinence, such that urine discharged or draining from the patient's bladder will run through the catheter and into the container. Urine incontinence, however, is normally the result of weak muscles in the walls of the urethra, these muscles, which have a valve function, having been weakened by surgical operation or at birth or through some other cause. Incontinence can be reduced or alleviated by a successive build-up of the muscle in the urethra wall. This remedy requires exercising the muscles involved, however.

It will be understood that when a person suffering from incontinence is fitted with urine removal apparatus of the aforesaid kind with which urine flows continuously from the bladder into the container, the bladder will never be filled, i.e. the bladder is almost always empty, and the aforesaid muscles can never be properly exercised.

Another drawback with apparatus with which urine discharges continuously from the bladder is that the conventional containers are dimensioned to accommodate a relatively small volume of urine, say about 0.2-0.3 l, and are made of a flexible material. When filled or partly filled with urine, such a container becomes bulky and relatively extended and when supported along

the leg of the user is highly troublesome and uncomfortable.

5 A specific object of the present invention is to provide an improved apparatus or system of the kind described in the introduction which will avoid the aforesaid drawbacks with respect to catheter appliances intended for internal use by women, particularly women who suffer from incontinence.

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The improved system is characterized in that the means by which the catheter tube is fixated in the urethra includes a first non-rigid, compliant collar which is located on the outer surface of the tube, concentrically with the longitudinal axis thereof, in the region of the tube opening that coacts with the bladder, and which is intended to sealingly abut the inner wall of the urethra, and further includes a second non-rigid, compliant collar which is located adjacent to or near the outlet opening of the catheter tube, such as to form a restriction which limits the extent to which the tube can be inserted into the urethra; and is further characterized in that the urine collecting container is divided into mutually communication sections or compartments.

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Firstly, the length of the improved catheter tube is adapted accurately to the length dimension of the female urethra and the tube can be inserted into and removed from the urethra with comparative ease. The rearwardly located collar also functions as a means for indicating to the user that the catheter tube has been inserted to an extent at which said collar lies in sealing abutment with the body in the region of the urethra orifice. At the same time, the collar which is

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located nearest the inlet opening of the catheter tube will be oriented such that the peripheral surface of the collar abuts urethra musculature and therewith ensures that an effective seal is obtained. The cross-sectional dimensions of the catheter tube are uniform overall and the tube has an outer diameter which is only slightly smaller than the diameter of the urinary tract or urethra.

- 10 Secondly, the indirect connection of the catheter tube to the urine collecting container or to the drainage hose, i.e. the hose which connects the catheter tube to the container, is provided with known, manually operable means for blocking the urine passageway and there-  
15 with prevent the flow of urine into the container. This enables urine to build up in the bladder, so that the muscles of the urethra or urinal tract will be subjected to the muscle-strengthening exercises required for remedying incontinence. It will be understood that when  
20 the catheter tube is connected directly to the container, similar blocking means can be provided on the catheter tube, e.g. in the region of the catheter opening located externally of the body of the wearer.
- 25 Thirdly, the container intended for the temporary storage of urine is composed of compartments which function to achieve uniform distribution of the urine entering the container. Despite its flexibility, the container will retain an optimal flat configuration when filled,  
30 therewith causing less trouble and discomfort to the wearer than known containers intended for this purpose.

The thus improved apparatus or system has a surprisingly pronounced psychological effect on the user, while,  
35 at the same time, automatically stimulating weakened

urinal musculature.

The provision of manually operable means for closing the drainage hose (or catheter tube) enables the user  
5 to interrupt or commence emptying of the bladder at will.

Advantageous embodiments and further developments of the inventive apparatus are defined in the depending  
10 Claims.

The invention will now be described in more detail with reference to an exemplifying embodiment of the inventive apparatus or system illustrated in the accompany-  
15 ing schematic drawing. Other features of the improved urine drainage apparatus or system will also be apparent from the following description.

In the accompany drawing,  
20 Figure 1 illustrates schematically and in axial section a catheter tube for internal use;

Figure 2 illustrates schematically the tube of Figure 1  
25 connected detachably to a drainage hose;

Figure 2a illustrates schematically exemplifying means for preventing urine from flowing into a urine collecting container;

30 Figure 3 illustrates from above part of the drainage hose of Figure 2 or Figure 2a detachably connected to a urine collecting container; and



Figure 4 is a sectional view taken in the direction of the arrow IV-IV.

The length of the female urethra is normally about  
5 4 cm. The catheter tube 10 is of flexible or bendable  
construction and has a total length which is greater  
than these 4 cm. The catheter tube 10 will preferably  
have a length of about 5-7 cm, or longer. The outer  
10 diameter of the tube 10 will, of course, be slightly  
smaller than the diameter of the female ure-thra and  
the outer surface of the tube will have optimal smooth-  
ness. The tube 10 has an inner diameter which is uni-  
form throughout the whole length of the tube and pre-  
sents a first opening 11, the inlet opening, and a  
15 second opening 12, the outlet opening. The tube 10 is  
provided adjacent the first opening 11, or in the re-  
gion of said first opening 11, with a collar 13 in the  
form of a truncated cone and, comprising a cylindrical  
peripheral part 14 and a part 15 which tapers towards  
20 the ends of the conical part 14. As will be seen from  
Figure 1 and Figure 2, the conical part 14 of the col-  
lar slopes rearwardly towards the outlet opening 12 of  
the catheter tube 10, such as to form an acute angle,  
optionally an angle of between 50 and 75°, between the  
25 peripheral surface of the catheter tube 10 and the base  
of the conical part 14. In the illustrated embodiment,  
the collar 13 borders essentially on the inlet opening  
11, although said collar may alternatively be posi-  
tioned somewhat further down on the tube 10, i.e.  
30 slightly nearer the outlet opening 12. The collar 13  
may, advantageously, be made of silicone rubber or some  
other material equally as friendly to the body of the  
wearer, since this collar is intended to be material  
located in the urethra of the female wearer. The con-  
35 cal part 14 of the collar 13 is elastically deformable,

and the end of the tapering part 15 is rounded-off.

In accordance with one embodiment of the invention, the conical part 14 of the collar 13 may be hollow and  
5 accommodate a viscous fluid, for instance a hormone preparation, in which case the walls of said conical part 14 will consist of a material that is permeable to the fluid in question. With each movement made by the  
10 wearer, the conical part 14, which when the catheter tube 10 is inserted lies against the musculature of the urethra, will be subjected to bending or deformation forces which result in the creation of an overpressure within the hollow space of the conical part 14, whereby  
15 the viscous fluid enclosed therein will be forced out through the permeable wall of the conical part 14 and absorbed by the body of the wearer. The conical part 14 of the collar 13 will normally have a radial extension of about 6 mm, measured from the periphery of the catheter tube.

20 The aforementioned viscous fluid can be introduced into the conical part 14 during industrial manufacture of the catheter tube 10.

25 As illustrated in Figures 1 and 2, the catheter tube 10 includes a second collar 16 which is located downstream of the collar 13 and the construction of which is essentially the same as the construction of the first collar 13 and has a radially extending, elastically  
30 deformable conical part 17. The vertical extension h-x of the second collar 16, however, is smaller or much smaller than the vertical extension h of the conical part 14 of the first collar 13.  
The positions of the two aforescribed collars 13 and

16 are such that respective conical parts 14, 17 will abut muscular parts of the wall of the female urethra.

The catheter tube 10 also has a third collar 18 located in the region of the outlet opening 12, preferably slightly upstream of said outlet opening. The circular-conical part 19 of the third collar 18 is essentially of uniform thickness and is preferably of solid construction. The collar 18, or conical part 19, has a vertical extension  $h + x$ , i.e. a vertical or radial extension which is greater than the vertical or radial extension of the first collar 13. The conical part 19 widens in the upstream direction of the catheter tube 10, and by making the conical part 19 compliant, said part can be brought into abutment with the urethra or urinal tract in the vicinity of the outlet orifice thereof. The conical part 19 of the third collar 18 is preferably more rigid than the conical part 17 and 14 of the respective second and first collars 16 and 13, thereby to enable the conical part 19 to form a stop means and thereby indicate that the tube 10 shall be inserted into the female urethra to an extent such that the conical part 19 comes into abutment with or essentially into abutment with that part of the female's body located in the region of the urethra outlet orifice. The radial extension of the third collar 18 will normally be such as to render it impossible in practice to tube the catheter tube 10 further than what is intended.

The aforescribed catheter tube 10 can be readily handled by the user without the assistance of urologically trained personnel. When the tube 10 is inserted into the urethra of the female user, the conical part 14 of the first collar 13 will bend in the downstream

direction, i.e. rearwardly towards the outlet opening 12, and slide against the urethra wall. Subsequent to inserting the catheter 10 to its optimal position, the catheter is withdrawn slightly, whereby the conical part 14 of the first collar 13 will attempt to bend in the opposite direction. The catheter tube is withdrawn only to a small extent sufficient for the conical part 14 to lift and take approximately the position illustrated in Figure 1, wherewith the rounded edge of said part 14 will sealingly abut the muscular wall of the urethra while fixating the tube 10 in this position at the same time. Normal movement of the user, such as movement from a standing to a sitting or lying position, will not change the adopted position of the catheter tube 10 in the urethra. In the case of the aforesaid alternative embodiment in which the conical part 14 and/or the conical part 16 contains a fluid substance, such movement will cause said substance to permeate through the walls of said conical parts.

As will be seen from Figure 2, the inventive system is provided with known means 18' operative to prevent urine flowing out through the opening 12 and into the container. The reason why such means is provided will be explained in the following.

In the embodiment illustrated in Figure 2, the aforescribed catheter tube 10 is fixedly or detachably connected to a flexible drainage hose 20, one end of which is connected in a known manner to the tube and which may be provided somewhere along its length with means for interrupting the flow of urine through the hose and thereby, for reasons already mentioned, thereby causing a build-up of urine in the bladder of the user. Such means may, for instance, have the form of a

conventional clamp 21 (Figure 2a) which is clamped firmly around two hose parts bent back one upon the other. The closure means may also have the form of a known valve device, as indicated at 22 in Figures 2 and 2a.

The other end of the illustrated drainage hose 20 is connected to a urine collecting container, generally referenced 23, which is formed from a stretchable synthetic material. Thus, the container 23 will be flat, or essentially flat when not in use. The container 23 has an elongated configuration, with a smoothly rounded external shape. Connected to the container itself are two mutually opposing pieces 24, 25 provided with suspension slots 26, by means of which the container can be hung or hooked for instance, and a scale 26' for indicating the volume of liquid in the container.

The actual liquid accommodating part, referenced 23' in Figure 3, of the container 23 comprises a plurality of compartments 33 arranged within the container part 23'. These compartments 33 are in mutually spaced relationship, so as to form a plurality of liquid accommodating spaces or channels 33' which communicate with one another. This compartment arrangement ensures that the body liquid entering the container will be distributed uniformly between the various compartments or channels, whereby the container, even when full or partially full, will be easier to carry and less voluminous than conventional containers. The rounded corners of the container 23 also cause the pressure within the container to be distributed more uniformly while an arrangement in which the container lacks sharp edges will reduce the risk of damage to the container. Connected to the bottom of the container 23 is a short

drainage pipe 27 which incorporates a known, manually operable valve means 29 in the vicinity of the outlet opening 28 of the container. This enables the container 23 to be emptied whenever desired.

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The liquid accommodating part 23' of the container 23 may also advantageously be provided with an internally arranged reagent 30 of a known kind capable of being read externally of the container, so as to enable the possible occurrence of undesirable bacteria flora to be established.

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Fitted to the upper end of the liquid collecting container 23 is a suitable non-return valve, for instance a check valve of the kind illustrated and described in my U.S. Patent Application No. 134,942. It will be obvious to those skilled in this art that any type of known valve which permits fluid to flow in solely one direction can be used. The improved container 23 is also provided with an overpressure valve indicated at 31. In its simplest form, this overpressure valve 31 may consist of a circular region formed integrally with the container material and consisting of a gas-permeable material, for instance material retailed under the registered trademark GOR-TEX. Gas present in the container 23 departs through the valve 31, thereby enabling the container to be filled to capacity, which has not been possible with hitherto known containers intended for this purpose.

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It will be understood that the aforescribed container 23 can be used for both male and female requirements, since it is solely the catheter tube which is configured particularly for insertion into the female urethra. Consequently, the container 23 can be combined

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with any other type of (known) catheter device or any other form of urine transfer device.

Although the specific object of the invention is to  
5 remedy, alleviate or guard against incontinence in  
women, it will be obvious to one skilled in this art  
that the improved system and the mutually coacting  
units or devices included in said system can replace  
highly advantageously other units and devices of pre-  
10 sent-day similar systems.

It also lies within the scope of the present invention  
to combine the catheter of said apparatus with a known  
urine collecting container, and also to combine novel  
15 the container of the described system with a known or  
conventional catheter.

C l a i m s

1. A system for the period or continuous drainage of urine from the bladder of females said system comprising  
5 ing firstly a urine catheter tube which includes an enlongated, hollow, flexible so-called catheter tube (10) intended for insertion into the urethra of a female patient, one open end of the catheter tube (10) communicating with the bladder and therewith functioning  
10 ing as an inlet opening for urine present in said bladder, and the other open end of which functions as an outlet opening for urine draining from the bladder, said catheter tube (10) including means for fixating said tube within the urethra, and secondly a container  
15 (23) which is connected to the outlet opening of the catheter tube either directly or indirectly and which is intended for collecting and temporarily storing urine draining from the bladder, said container (23) being provided in the region of said inlet with valve  
20 means which permit urine to flow from the catheter tube (10) into the container (23) but prevent the flow of urine in the reverse direction, and the lower end of said container (23) being provided with means (28, 29) for emptying said container of its contents,  
25 c h a r a c t e r i z e d in that the means for fixating the catheter tube (10) in the urethra includes a first compliant collar (13) which is located on the outside of the tube in the region of the opening coacting with the bladder and which is concentric with the  
30 longitudinal axis of the tube (10), said first collar being intended to sealingly abut the urethra wall, and further includes a second compliant collar (18) which is located adjacent to or in the vicinity of the region of the outlet opening of the catheter tube (10) such as  
35 to form means for restricting the extent to which the



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tube (10) is inserted into the urethra; and in that the urine collecting container (23) is divided into mutually communicating sections.

5 2. A system according to Claim 1, c h a r a c -  
t e r i z e d in that the first and the second collars  
(13, 18) form a unit together with the catheter tube  
(10).

10 3. A system according to Claim 1 or 2, c h a r -  
a c t e r i z e d in that the conical parts (14 and  
19) of respective first and second collars (13 and 18)  
widen in mutually opposite directions.

15 4. A system according to one or more of the preceding  
claims, c h a r a c t e r i z e d in that the conical  
part (14) of the first collar (13) has a smaller radial  
extension than the conical part (19) of the second  
collar (18).

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5. A system according to any one of the preceding  
claims, c h a r a c t e r i z e d by a third collar  
(16) having a conical part (17) which widens in the  
same direction as the conical part of the first collar  
25 (13) and having a radial extension which is smaller  
than the radial extension of the conical part (14) of  
the first collar (13); and in that the third collar  
(16) is located between the first and the second col-  
lars (13 and 18).

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6. A system according to one or more of the preceding  
claims, c h a r a c t e r i z e d in that the conical  
parts (14 and 17) of the first (13) and/or the third  
(16) of said collars enclose a space for the accommoda-  
35 tion of a liquid which, when the catheter tube (10) is

in use, departs through permeable walls of the conical part or parts (14 or 17) when subjected to pressure.

5 7. A system according to any one of the preceding claims, characterized in that the conical part (19) of the collar (18) is solid.

10 8. A system according to any one of the preceding claims, characterized in that the catheter tube (10) has the same cross-sectional area throughout the whole of its length.

15 9. A system according to Claim 1, characterized by a drainage hose (20) which connects the catheter tube (10) to the urine collecting container (23).

20 10. A system according to Claim 9, characterized in that the drainage hose (20) and/or the catheter tube (10) is or are provided with means for preventing urine from flowing into the container (23).

25 11. A system according to Claim 1, characterized in that the container (23) is provided in the region of its upper part with valve means (31) operative to open at a predetermined overpressure created by urine present in the container and to restore the pressure balance in the container (23)  
30 (ambient pressure).

12. A system according to Claim 11, characterized in that said valve means (31) is located upstream of the check valve means.

13. A system according to Claim 1, c h a r a c -  
t e r i z e d in that the container (23) is elongated  
and that division of the container into compartments  
(33) is effected essentially in the longitudinal direc-  
5 tion of the container.

14. A system according to Claim 1, c h a r a c -  
t e r i z e d in that the container (23) is elongated  
and in that division of the container into compartments  
10 (33) is effected essentially in the transverse direc-  
tion of the container.

15. A system according to Claims 1, 13 or 14,  
c h a r a c t e r i z e d in that the compartments  
15 (33) in the container (23) are formed by narrow strips  
of material connected to mutually opposing inner walls  
of the container (23) and extending along and/or across  
the container; and in that each of said strips has a  
length which is at least half the length and/or the  
20 width of the container (23).

16. A system according to one or more of Claims 1, 13,  
14 or 15, c h a r a c t e r i z e d in that the con-  
tainer (23) is provided with a reagent substance (30)  
25 which is visible externally of the container and opera-  
tive to reveal the possible presence of bacteria flora.

17. A system according to one or more of the preceding  
claims, c h a r a c t e r i z e d in that the con-  
30 tainer (23) is provided with a scale (26') for indicat-  
ing the volume of liquid present in the container.

18. A system according to one or more of the preceding  
claims, c h a r a c t e r i z e d in that the urine  
35 collecting container (23) is combined with a catheter

tube of a kind different to that described in the present specification.

19. A catheter tube included in the system according to one or more of the preceding claims.

20. A container included in the system according to one or more of the preceding claims.

21. A catheter (10) for human use comprising an elongated, flexible tube intended for insertion into the urethra of a patient, one open end of the catheter tube (10) being intended for communication with the bladder and therewith function as an inlet opening for urine present in the bladder, and the other end of said catheter tube being intended to function as an outlet opening for urine flowing from the bladder, said catheter tube (10) including means for preventing unintentional removal of the catheter from the urethra, said catheter being connected to a urine collection container, either directly or indirectly, characterized in that the means for fixating the catheter tube in the urethra includes a first compliant collar (13) which is located on the outside of the tube in the region of the opening coacting with the bladder and which is concentric with the longitudinal axis of the tube (10), said first collar being intended to sealingly abut the urethra wall, and further includes a second compliant collar (18) which is located adjacent to or in the vicinity of the region of the outlet opening of the catheter tube (10) such as to form means for restricting the extent to which the tube (10) is inserted into the urethra; and in that the urine collecting container (23) is divided into mutually communicating sections.

22. A container for the temporary storage of urine discharging from a human being, said container (23) being made of a flexible material and having an inlet end and an openable and closeable outlet end, said  
5 container being provided in the region of said inlet end with valve means which function to permit liquid to flow into the container interior but to prevent liquid from flowing in the opposite direction, c h a r a c -  
t e r i z e d in that the liquid accommodating inter-  
10 ior of the container (23) is divided into mutually communicating sections, which preferably extend in the longitudinal direction of the container (23).

23. A container according to Claim 22, c h a r a c -  
15 t e r i z e d in that the container interior is provided with externally visual and readable reagent means (30), for instance litmus paper, operative to reveal the possible presence of undesirable bacterial in the urine.

1/1

Fig. 1

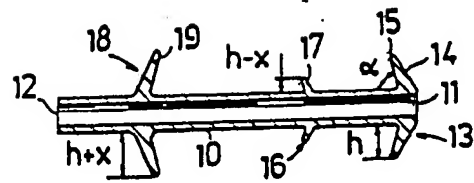


Fig. 2

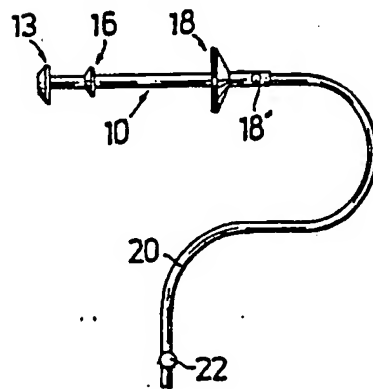


Fig. 2a

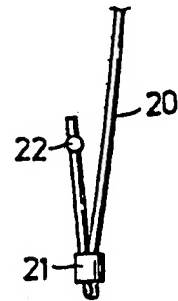


Fig. 3

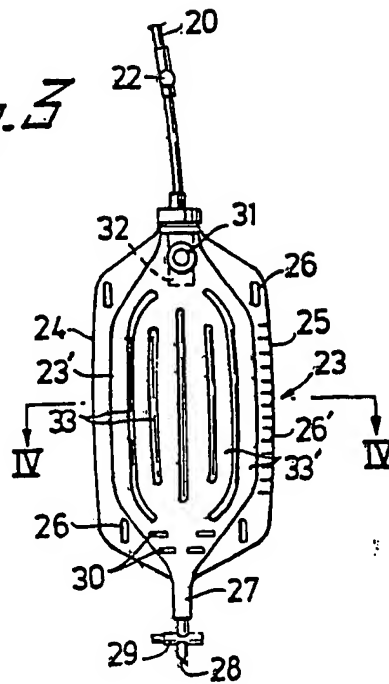
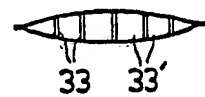


Fig. 4



# INTERNATIONAL SEARCH REPORT

International Application No PCT/SE 90/00458

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (If several classification symbols apply, indicate all) <sup>6</sup> According to International Patent Classification (IPC) or to both National Classification and IPC IPC5: A 61 F 5/455, A 61 M 25/00						
<b>II. FIELDS SEARCHED</b> <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black;">Minimum Documentation Searched<sup>7</sup></div> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%; border-bottom: 1px solid black;">Classification System</td> <td style="border-bottom: 1px solid black;">Classification Symbols</td> </tr> <tr> <td style="height: 40px; vertical-align: bottom;">IPC5</td> <td style="vertical-align: bottom;">A 61 F; A 61 M</td> </tr> </table>			Classification System	Classification Symbols	IPC5	A 61 F; A 61 M
Classification System	Classification Symbols					
IPC5	A 61 F; A 61 M					
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in Fields Searched <sup>8</sup>  SE,DK,FI,NO classes as above						
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT<sup>9</sup></b>						
Category *	Citation of Document, <sup>11</sup> with indication, where appropriate, of the relevant passages <sup>12</sup>	Relevant to Claim No. <sup>13</sup>				
X  A   A  A  A	SE, B, 386365 (L BRENDLING) 9 August 1976, see the whole document  <div style="text-align: center;">--</div> US, A, 3721243 (D. HESTERMAN ET AL) 20 March 1973, see figure 3 <div style="text-align: center;">--</div> WO, A1, 8200767 (CHILD LABORATORIES INC) 18 March 1982, see figures 20-21 <div style="text-align: center;">--</div> FR, A, 2023763 (AMERICAN HOSPITAL SUPPLY CORPORATION) 21 August 1970, see figure 2 <div style="text-align: center;">--</div>	22   1,9-10, 13,15, 20-21   1,9,13, 20-22   1-8,19, 21   1-3,7-9, 19,21				
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>* Special categories of cited documents:<sup>10</sup></p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&amp;" document member of the same patent family</p> </div> </div>						
<b>IV. CERTIFICATION</b>						
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report					
25th September 1990	1990 -10- 0 1					
International Searching Authority	Signature of Authorized Officer					
SWEDISH PATENT OFFICE	Leif Karnsäter <i>Leif Karnsäter</i>					

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
A	FR, A, 586018 (M. LOUIS-MARIE-CLÉMENT CHARNAUX) 13 March 1925, see figure 6 --	1,19, 21
A	SE, B, 380176 (ASTRA-SJUCO AB) 3 November 1975, see figure 1 -- -----	1,8,19, 21



## FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☒ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE<sup>1</sup>

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers....., because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claim numbers.....<sup>18</sup> because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:  
The technical features of the invention are missing /see PCT Rule 6.3b(i))

3. ☐ Claim numbers....., because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING<sup>2</sup>

This International Searching Authority found multiple inventions in this international application as follows:

Claims 1-18 concerning a system. Claim 17 concerning a catheter tube.  
Claim 20 concerning a container. Claim 21 concerning a catheter. Claims 22 and 23 concerning an independent container. (See PCT Rule 13.2).

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims. It is covered by claim numbers:

4. ☒ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

## Remark on Protest

- ☐ The additional search fees were accompanied by applicant's protest.  
☐ No protest accompanied the payment of additional search fees.

**ANNEX TO THE INTERNATIONAL SEARCH REPORT  
ON INTERNATIONAL PATENT APPLICATION NO. PCT/SE 90/00458**

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the Swedish Patent Office EDP file on 90-08-28. The Swedish Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
SE-B- 386365	76-08-09	CA-A- 1038252	78-09-12
		DE-A-C- 2435945	75-02-13
		FR-A-B- 2238468	75-02-21
		GB-A- 1471353	77-04-27
		JP-C- 884397	77-09-30
		JP-A- 50033692	75-03-31
		JP-B- 52012517	77-04-07
		SE-A- 7310331	75-01-27
		US-A- 3926233	75-12-16
US-A- 3721243	73-03-20	NONE	
WO-A1- 8200767	82-03-18	AU-D- 7588581	82-03-31
		CA-A- 1163592	84-03-13
		EP-A- 0059209	82-09-08
		US-A- 4346714	82-08-31
		US-A- 4385633	83-05-31
FR-A- 2023763	70-08-21	DE-A- 1958561	70-06-11
		GB-A- 1265033	72-03-01
		US-A- 3583391	71-06-08
FR-A- 586018	25-03-13	NONE	
SE-B- 380176	75-11-03	DE-A- 2357308	74-05-30
		GB-A- 1442144	76-07-07
		US-A- 3896804	75-07-29